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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,898	04/15/2004	William J. Boyle	A-451N	8965

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,898	BOYLE, WILLIAM J.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58,59,61-63,65-68 and 71-73* is/are pending in the application.

4a) Of the above claim(s) *72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58,59,61-63,65,68,71 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/10 has been entered.

2. Applicant's election with traverse of human antibody in the reply filed on 11/23/10 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because the species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species (aka human versus chimeric versus humanized antibodies). In addition, these species are not obvious variants of each other based on the current record. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries). The requirement is still deemed proper and is therefore made FINAL.

3. Claim 72 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/23/10.

4. The abstract of the disclosure is objected to because it does not disclose the claimed invention (aka the method of claim 58). Correction is required. See MPEP § 608.01(b).

5. Applicant is required to update the status of all US applications disclosed in the instant application.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The rejection of claims 58-62,64-68 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

8. Claims 58,59,61,62,65-68,71,73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the methods of claims 58,59,61,62,63,65-68,71,73. The claims encompass use of OPGbp or a soluble form thereof wherein original claim 43 does not disclose use of a soluble form of OGPbp as the form of OGPbp in said assay. In addition, orginal claim 43 is restricted to use of a "cell culture" wherein claim 58 does not specifically recite use of a cell culture system. Regarding applicants comments about the cited paragraph on page 26 of the specification, said paragraph is limited to a disclosure of compounds which block the interaction of OPGbp and ODAR wherein the claimed method encompasses use of compounds which act view mechanisms other than blocking the interaction of OPG and ODAR. The in vitro assays referred to on page 27 of the specification refer to assays for measuring OPGbp binding to ODAR. The claimed method encompasses use of compounds which act via mechanisms other than blocking the interaction of OPG and ODAR. The disclosure referred to on page 29 also refers to compounds which decrease complex formation of OGPbp and ODAR on ODAR bearing cells. The claimed method encompasses use of compounds which act via mechanisms other than blocking the interaction of OPGbp and ODAR. Example 8 in the specification is limited to the use of a specific cell culture system with specific ingredients for studying the interaction of

OPGbp and OPG. Furthermore, it indicates that M-CSF or stroma ST2 cells and dexamethasone are required for said cell culture system wherein said ingredients are not recited in the claims under consideration. In addition, said Example is limited to the use of mouse OPGbp wherein the claims recite use of compounds that bind human OPGbp. Regarding applicants comments about the specification, page 30, the cited passage discloses that: "Compounds which increase or decrease the interaction of OPG binding protein with ODAR may also be evaluated for in vivo activity by administration of the compounds to mice followed by measurements of bone density using bone scanning densitometry or radiography.". Thus, said passage is limited to a description of compounds which decrease the interaction of OPG binding protein and ODAR, wherein the claims under consideration are not so limited. Regarding the specification, page 23, the cited passage is limited to an in vitro method wherein OPGbp/ligand binding is measured. Said passage also includes an additional step wherein the compound is measure for agonist or antagonist activity, but there is no description as to how said activity is measured.

There is no written description of the scope of the claimed inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

Applicant has argued that the claimed invention is obvious in view of the disclosure. However, obviousness is not the appropriate standard with regards to issues of written description. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.. . ."), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

9. The rejection of claim 60 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office action is withdrawn in view of the cancellation of said claim.

10. Regarding the application of prior art, the claims raise the issue of new matter as per above and also lack support in the parent applications to which priority is claimed and therefore they are not entitled to priority to the parent applications for which priority is claimed.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 58,59,61-63,65-68,71,73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle (US Patent 6,316,408) in view of Choi et al. (WO 02/16551). Applicants arguments have been considered and deemed not persuasive.

Boyle teaches OPGbp of SEQ. ID. No. 4 and the various fragments recited in the claims (see columns 7-9). Boyle teaches that compounds that interact with OPGbp can be screened by measuring the binding of said compound to OPGbp and then further characterizing the ability of said compound to decrease OPGbp activity (see column 11, third paragraph). Boyle teach that such compounds can include antibodies such as recombinantly made human antibodies(see column 9, penultimate paragraph). Boyle teaches that OPGbp binds to ODAR (see columns 12-15). Boyle et al. do not teach the method of claim 58 using osteoclast formation in vitro wherein the test compound binds human OPGbp. Choi et al. disclose in vitro assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said protein (see pages 18-20). Boyle disclose that OPGbp effects osteoclast activity and bone resorption (see column 2, penultimate paragraph). Decreased bone resorption results in increased bone density. It would have been prima facia obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Boyle teaches that compounds that interact with OPGbp can be screened by measuring the binding of said compound to OPGbp and then further characterizing the ability of said compound to decrease OPGbp activity whilst Choi et al. disclose that in vitro assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said compound. One of ordinary skill in the art would have been motivated to do the aforementioned because Choi et al. disclose that in vitro assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said compound.

Applicants arguments regarding priority/new matter are addressed above.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is

(571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644